



# BIOCIDES FACT SHEET



Biocidal Products Directive  
Biocidal Products Regulations  
Control of Pesticides Regulations

**Issue No. 23**

**May 2005**

## **Purpose**

These Fact Sheets provide briefings for manufacturers, suppliers and users of active substances and biocidal products to help keep you up to date with developments in the Biocidal Products Directive (BPD) 98/8/EC and the Biocidal Products Regulations 2001. From May 2005 the Fact Sheets also incorporate information on the Control of Pesticides Regulations that would previously have appeared in the 'Pesticides Newsletter' – publication of the Newsletter has now ceased.

Fact Sheet 23 is **not** a revision of Fact Sheets Nos.1-22 but instead provides supplementary information and advice. If you would like copies of earlier Fact Sheets, they can be downloaded from our website - the website address is given at the end of this Fact Sheet.

## **Contents**

<b>General Information</b>	<b>Page</b>
<b>1. Changes to the Publication of the Biocides Fact Sheet and the Pesticides Newsletter.</b>	<b>2</b>

### **Biocides - European Activities**

<b>2. Report from the 18<sup>th</sup> Meeting of the Competent Authorities (29-30 March 2005)</b>	
a. Update on the Manual of Decisions	3
b. Report from the Technical Meeting in March 2005	4
c. Procedures and Timescales 'Post Annex I Inclusion'	6
d. Third Review Regulation	6
e. Role of Chromium in Wood Preservation	6
f. General Note on Data Protection	6

g. Activities of the International Maritime Organisation (IMO) regarding the use of active substances for the treatment of ballast water	7
h. Study on Treated Articles	7
i. Pine Tar : New Information on Efficacy and Essential Use Derogation	7
j. Any Other Business	7

### ***Biocides - UK Activities***

3. The General Industry Charge	9
4. Teat Dips Clarification	9

### ***Control of Pesticides Regulations Specific Information***

5. Review of Data Required in Support of Products regulated under the Control of Pesticides Regulations.	9
6. Changes to Applications for Experimental Permits / Automatic Experimental Permits under COPR	11

<b><i>Useful websites and contact details</i></b>	<b>12</b>
---	-----------

---

## ***General Information***

---

### **1. CHANGES TO THE PUBLICATION OF THE BIOCIDES FACT SHEET AND THE PESTICIDES NEWSLETTER.**

Since 1988 the Biocides and Pesticides Unit of HSE has produced the 'Pesticides Newsletter', providing information on the requirements of the Control of Pesticides Regulations to product Approval Holders and other interested parties. In July 1997 we also began producing the Biocidal Products Directive Fact Sheets which were aimed at both the pesticides industry and the wider biocides industry that would be regulated under the Directive. These two publications have been produced in parallel for 8 years, and recently it has become apparent that, as the Directive begins to have a more prominent role in non-agricultural pesticides issues, so the amount of information that is specifically related to the Control of Pesticides Regulations has diminished, bringing into question the value of producing two separate publications.

When we asked the readership of both publications at the end of 2003 if they would have objections to them being merged, 91% of respondees said that they would not have any objections to a merger. Therefore we have ceased

publication of a separate 'Pesticides Newsletter' and have merged the information that would have appeared in the Newsletter into this Fact Sheet. We will maintain a separate section towards the end of the Fact Sheet for information that is specific to the Control of Pesticides Regulations, and our readers who do not have products that fall within the scope of these regulations can simply by-pass this section.

As product types are moved from regulation under the pesticides scheme to the biocides regime following the review of active substances, so the need for a Control of Pesticides Regulations section will decrease, and eventually we will drop this section altogether.

We also informed readers in the last issue of the Fact Sheet that the production schedule for this publication would now be more flexible, linking into the European schedule for Competent Authority meetings to allow us to provide more up-to-date information to the industry as soon as possible after the meeting. As the next CA meeting is scheduled for July we intend to publish the next issue of the Fact Sheet after that meeting.

---

## ***Biocides - European Activities***

---

### **2. REPORT ON THE 18<sup>TH</sup> MEETING OF THE COMPETENT AUTHORITIES (29-30 MARCH 2005)**

#### ***a). UPDATE ON THE MANUAL OF DECISIONS***

The new entries to the Manual were discussed with a view to an updated version being published, these entries were:

- Potassium formates in wood preservation
- Methyl bromide (see Any Other Business)
- An antifouling product previously considered in the Manual under 2.3.1.15.
- Medical devices - The Commission agreed to produce a guidance document on the borderline between medical devices and biocides as some Member States were having problems at national level.
- Processing aids – The Commission noted that processing aids in the production of food are outside the scope of BPD providing the product is fully eliminated, therefore these products must be dealt with by national rules (see AOB).
- Products used on animals – It was made clear that the entry in the Manual must state no medicinal claims can be made.
- Borderline between biocides, medicines and vet medicines – It was noted that the definition of what constitutes a biocide had changed,

Member States questioned this and the Commission agreed to redraft the definition.

The Commission will amend the Manual as necessary and publish the new version on the EC Environment Directorate webpage (address at the end of this Fact Sheet).

#### ***b). REPORT FROM THE TECHNICAL MEETING IN MARCH 2005***

The Commission reported back from the Technical Meeting (TM), one of the items that had been discussed was not on the TM agenda – the Competent Authorities were informed that a workshop has been set up to look at issues surrounding leaching tests (Week Commencing 13<sup>th</sup> June in Italy)

#### **The following agenda items were then discussed**

**i. Guidance on data requirements for pheromones** - There had been an Industry submission in response to the original paper from the UK, and Austria had hosted a subgroup of Member States which made proposals limited to the 4 pheromone active substances that had been notified. Discussions focused on the amount of environmental data required. It was agreed that the paper, once finalised, could be published on the ECB website.

**ii. Guidance on data requirements for essential oils** - The Commission will redraft a paper for agreement at the next Technical Meeting with thought given to the scope and title of the paper. Again this will be published once it has been completed.

**iii. Regulation (EC) 2229/2004 on the 4<sup>th</sup> stage of the review programme for active substances used in Plant Protection Products** - It was noted that some biocides active substances are contained on the 4<sup>th</sup> list for review under the Plant Protection Products Directive (91/414). The Commission encouraged discussion between Rapporteur Member States if they are different for the 2 Directives.

**iv. Guidance document on Technical Equivalence** - The UK are to produce a new version of this paper. It was thought that there would be a unification of BPD and PPPD requirements and that is still the long term goal although there are currently timing issues. Therefore in the short term there will be 2 papers, 1 for biocides and 1 for plant protection products.

**v. Procedures for handling the final stage of review process for active substances:**

Finalisation of review - The Commission noted the deadlines in the BPD must be met and highlighted the requirement for comparative assessment, ideally before Annex 1 inclusion. An issue was raised regarding how to classify the dossier with respect to disclosure. Member States could only refuse access to information that has a negative commercial value to the holder if it were disclosed (e.g. anything that would allow production to be

copied or impurities). The Commission's view was that there is not much that is not disclosable. The Rapporteur Member State and participant should agree under Article 19 what is confidential, these data should be in an annex to the Competent Authority report so should be easy to take out. All confidential data should have been identified in Completeness Check. The Commission will check issues surrounding dossier marking.

Classification & Labelling - The Commission noted that for classification and labelling (C & L), the Rapporteur Member State should liaise with their national colleagues who deal with C & L under the Dangerous Preparations Directive (DPD). If there is already an agreed classification under this Directive it should be used. If there is no agreed classification then the Rapporteur will propose one as part of the dossier evaluation, and if this is agreed by the other Member States - via the Qualified Majority Voting procedures – then that should be fed into DPD for consideration as an Adaptation for Technical Progress. Participants will have the opportunity to comment on the proposed classification to the Rapporteur Member State.

Timing of inclusion decisions - After discussion the meeting agreed that active substances would be put onto Annex I as they were agreed, in reality this would mean they were done in batches based on the frequency of the meetings, any non inclusion decisions made outside a meeting would be done immediately

**vi. Guidance on recording data protection periods for studies for active substances** – The Commission stated that this was a guidance document which, in their opinion was a correct interpretation of Article 12. For a study to be eligible for data protection a participant must have claimed data protection for that study as part of the dossier submission, and the RMS will need to go through old records to see if they have given protection for that study under any existing national rules. Other Member States will also have to confirm if the data are new to that Member State or not. The idea of a central database was suggested. The Commission noted that data protection is valid for all studies not just key studies.

CEFIC asked about studies sent to new Member States before they joined the EU. They also asked where such a database is to be held, as they don't want free riders to be able to use it. The Commission noted the same rules apply for new MS as old ones and that the issue of database had not been discussed. The Commission will redraft the paper with comments from Member States.

**vii. Data requirements for micro-organisms** - The Commission summarised the paper and comments were required by 15<sup>th</sup> April. The Commission will then prepare a draft Annex 6 on the basis of the PPPD annex.

### **c). PROCEDURES AND TIMESCALES 'POST ANNEX I INCLUSION'**

CEFIC introduced their letter on this issue, they want harmonisation and enforcement of products post Annex I, including an inventory as to what is on the market. CEFIC wanted a very simple notification process post Annex I inclusion to allow a period of time to get the dossier in whilst keeping products on the market. They noted that few companies will put together an application prior to Annex I listing, therefore time will be needed to get dossier in and evaluated. They also noted this was a compromise paper, between active notifiers and formulators with the knowledge that the data protection clock will be ticking. The Commission suggested it seems a lot of work for those Member States without current schemes and they are not sure if there is the legal power to require this. The Commission noted they do not like this “2 step process” and would prefer a date when all products must be authorised without a notification step. The UK welcomed CEFIC's paper, and noted they were looking at a minimalist 2-step approach, however several MS had reservations with this approach. The Commission, in summary, noted they would see if they can make the “notification” scheme proposed by CEFIC legal, but they are hesitant to propose this as it would lead to increased work and there may be challenges from those companies who have products taken off the market because they did not notify these products. Member States are to supply comments to the Commission on this issue.

### **d). THIRD REVIEW REGULATION**

The Commission presented an amended version of the document which highlighted all of the agreed changes, and various minor textual amendments were requested. **A final document was produced which was agreed by the Standing Committee in their meeting the following day.** A copy will be made available on the European Chemicals Bureau website.

### **e). ROLE OF CHROMIUM IN WOOD PRESERVATION**

The Commission noted Denmark's comments had been taken on board suggesting that there is evidence of biocidal activity. There were no other comments and the paper's recommendations that applications are treated on a case-by-case basis stands.

### **f). GENERAL NOTE ON DATA PROTECTION**

Finland had changed the data requirements of their national legislation for antifouling products to bring them in-line with the requirements of the Directive. However, this paper highlighted the issue that the Finnish request for data was before the date the Directive came into force. The Legal view was that it was therefore a national rule, and consequently the data protection clock is ticking and the studies will not get extra data protection under BPD. The Commission will therefore amend Article 12 to change the date of force of the Directive's data protection such that the data submitted to Finland will be deemed to have been submitted for the purposes of the Directive, and therefore will be eligible for the Directive's period of data protection.

**g). ACTIVITIES OF THE INTERNATIONAL MARITIME ORGANISATION (IMO) REGARDING THE USE OF ACTIVE SUBSTANCES FOR THE TREATMENT OF BALLAST WATER**

The Commission highlighted an IMO requirement for approval for ballast water systems, they are not happy about the lack of consultation. The Mediterranean and Black Sea face problems with algae imported from elsewhere in ballast water. A system will be introduced by the IMO, the details need to be agreed, but what is currently proposed is not in line with the BPD. There is little time for Member States to influence proceedings as the next IMO meeting is in July when the system will be adopted. Comments were required by 15<sup>th</sup> April, and Member States need to lobby nationally, whilst the Commission will contact Directorate General Transport to ask for more time to consider a system based on the BPD.

**h). STUDY ON TREATED ARTICLES**

This paper sets out the basic requirements for a tender for a project to look at the issue of treated articles. Some Member States noted that they had information from national studies which could be fed into the project, the Commission asked for comments by 15<sup>th</sup> April, it will then produce a formal notice of tender.

**i). PINE TAR : NEW INFORMATION ON EFFICACY AND ESSENTIAL USE DEROGATION**

The Commission noted there are 2 questions with this issue:

- Does Pine Tar have efficacy as a wood preservative?
- Does Pine Tar act by physical or chemical means?

Depending on the answers to these questions an essential use application will need to be submitted. Further work is required to answer these questions, Sweden have information which they will submit to the Commission. It was noted that what is agreed here will set precedents for future applications. Member States including the UK noted they also have some use of pine tar. The Commission indicated that ultimately they could insert a derogation into the Directive for the use of pine tar on historic buildings and boats.

**j). ANY OTHER BUSINESS**

**i. Information regarding new legislation on Regulation (EC) No 853/2004 on specific hygiene rules for food of animal origin and status of processing aids**

The Commission noted there are biocides (disinfectants) used as processing aids. Article 1.2 of BPD states products are exempt if they are “defined or included in scope of other directives”. Processing aids are defined in Directive 89/107 (although they are out of scope of it). Therefore they are exempt from BPD.

**ii. Information on discussions within the legislation on materials in contact with food on the use of antimicrobial substances in such materials**

The Commission noted proposals from Industry to add biocides to surfaces which come into contact with food e.g. conveyor belts. These products are covered by Directive 89/107. The Commission asked EC Agriculture Directorate to follow BPD when authorising products, however they do not consider the environment under 89/107.

**iii. Discussion of appropriate legislation for use of methyl bromide in pre-shipment quarantine treatment of wood packaging material**

Answers to a UK scope question indicated a clear line that this use is plant protection and so within the remit of the Plant Protection Products Directive as methyl bromide is only used to stop the spread of plant pathogens, if the treatment had other purposes then it would be biocidal. These uses are deemed to be essential so are acceptable under the Montreal Protocol. This decision will be fed into the Manual of Decisions and stands true for other situations where the sole use of the product is against plant pathogens.

**iv. Stopping the clock**

France tabled a room document asking for a delay for one of their dossiers, several other Member States mentioned issues with evaluations. The Commission noted that the deadlines in the Directive were fixed and Member States should endeavour to meet their deadlines. Stopping the clock should only be used as a last resort.

**v. Earthworms**

The UK noted that there are products used against worms to prevent casts on, for example, golf courses. It was agreed this use is biocidal, but into which product type should they be put? The consensus of the meeting was to change the definition of Product Type 16 from "molluscicides" to "molluscicides and other invertebrates". This requires a modification of the Directive.

**vi. PT 18 timings/Emission Scenario Documents**

CEFIC noted the Emission Scenario Document is expected in September which is too late for submission of dossiers for Product Type 18. They requested that the calculation method in the ESD should not be mandatory, other calculation methods are available and should be acceptable if there are no data. Participants should discuss with Rapporteur Member States as to what method to use.

- Next meetings:      Technical Meeting      - Week Commencing 13<sup>th</sup> June 2005  
                                 CA-Meeting                                      - 4/5 July 2005

---

## ***Biocides - UK Activities***

---

### **3. THE GENERAL INDUSTRY CHARGE**

The Biocidal Products Directive requires that the costs of running the biocides scheme are recouped from the biocides industry, and in the UK we intend to do this via direct fees for product authorisations/active substance reviews, and with the General Industry Charge (GIC) for other costs. Companies that registered their liability with HSE for the GIC will have recently received a letter explaining that we had discovered an error in the Biocidal Products Regulations in relation to the GIC. This meant that those companies who were liable due to them having placed biocidal products onto the UK market could not legally be charged the GIC, and will not be liable until the Regulations are amended to correct the error. HSE has therefore refunded the money paid by these companies for the GIC for 2003/04, and will not be charging them for 2004/05. The Regulations will be amended to correct the error.

Those companies that were liable for the GIC due to them being a manufacturer and a notifier of active substances that are placed on the UK market are not affected by this error. These companies are still liable for the GIC – though please note HSE is not going to increase your charge to make-up the shortfall.

### **4. TEAT DIPS CLARIFICATION**

In Fact Sheet No. 22 we gave a Report from the 17<sup>th</sup> Meeting of the Competent Authorities where Teat Dips were mentioned in 'Any Other Business' and we described them as being considered to be biocidal products. As a caveat to this we would like to point out that teat dips will be considered to be biocidal products in the UK, providing individual products are not considered to be veterinary medicines by the Veterinary Medicines Directorate. You should seek VMD's advice on this before approaching HSE.

---

## ***Control of Pesticides Regulations Specific Information***

---

### **5. REVIEW OF DATA REQUIRED IN SUPPORT OF PRODUCTS REGULATED UNDER THE CONTROL OF PESTICIDES REGULATIONS 1986.**

BPU has examined the resources that are being used for the first phase of the BPD review programme, and has considered the work that will be required for the second phase that begins next year, as well as the resource that will be needed to set up the authorisation system for biocidal products. In parallel to this we have looked at the work we do under COPR to identify which work must continue as a priority, and which can reasonably be considered lower priority. This has allowed us to transfer some of our resource to the new

regulatory system required under the BPD. As a result changes have been implemented in the following areas:

#### A. POST APPROVAL/REVIEW DATA REQUIREMENTS

##### **Where data have been submitted**

The following post approval/review data requirements will be given priority:

- Those that are relevant to human health
- Those on active substances that will continue on the market beyond September 2006

The following post approval/review data requirements will be given lower priority:

- Those that do not have a human health concern
- Those on active substances which were only identified, and which will therefore not continue on the market after September 2006

##### **Where data have not been submitted**

The following post approval/review data requirements need not be addressed for the continued approval of a product under COPR:

- Those that do not have a human health concern, which have a submission deadline after 30 September 2005, and/or contain active substances that have to be removed from the market in September 2006.

***Such data need not be submitted to BPU***

The following post approval/review data requirements still require addressing for the continued approval of a product under COPR:

- Those with a deadline prior to 30 September 2005

***Such data still need to be submitted to BPU***

These data will be evaluated as resources allow.

From now on BPU will set post approval/review data requirements in line with the above policy.

#### B. NEW SOURCE DATA REQUIREMENTS

Due to the improving standards (such as Good Laboratory Practice) required for various physical chemistry data in support of a new source application, the value placed on spectral data has been reduced. As such the requirement to submit these data is no longer necessary. This change will be reflected in the following documents:

- New Source Guidance
- New Source Proforma

These documents are available on our website ([www.hse.gov.uk/pesticides](http://www.hse.gov.uk/pesticides))

**C. ACTIVE INGREDIENT TECHNICAL SPECIFICATIONS AND LETTERS OF INTENT (TO SUPPLY)**

BPU has now completed the review of its policy concerning the requirement to provide technical specifications and letters of intent (to supply). From now on BPU will require the following information to be submitted in support of an application for a product approval under COPR:

**For all active ingredients**

- A letter of intent (to supply)

**For active ingredients still under data protection**

- A letter of access from the data owner confirming that the applicant has access to the data package that was accepted by the Advisory Committee on Pesticides (ACP)

**For active ingredients no longer under data protection**

- An acceptable active ingredient technical specification (specific to the stated manufacturer) unless BPU currently holds one

**For active ingredients that have not been reviewed by the ACP**

- The manufacturing site [manufacturer's name and site address]
- The certified minimum purity (% w/w) for the active ingredient

**D. SAFETY DATA SHEET (SDS)**

In order to minimize duplication and delays, BPU will no longer automatically ask for a SDS to be submitted with each product application. BPU currently holds SDSs to cover the majority of materials on the market. However if we do not hold an SDS for a material listed on your application form, you will be asked to submit one for that material.

**6. CHANGES TO APPLICATIONS FOR EXPERIMENTAL PERMITS / AUTOMATIC EXPERIMENTAL PERMITS UNDER COPR**

Applicants are reminded that automatic experimental permits (AEP's) and experimental permits (EP's) can only be granted under COPR for existing substances for the purpose of research/development or in experimental trials.

Existing substances are those that have been either identified or notified under the Biocidal Products Directive (BPD), as listed by the Second Review Regulation (2032/2003) (available in the Legislation section of the European Chemicals Bureau website - <http://ecb.jrc.it/biocides/>).

For an AEP, applicants will now be requested to supply the EC, CAS and PT (product type) numbers as detailed in the Second Review Regulation.

For an EP this check will be carried out by BPU as part of the fee-banding exercise where this information has not been supplied.

If you have any questions regarding this issue please contact our Approvals Group at the address at the end of this Fact Sheet.

---

### ***Useful Websites and Contact Details***

---

As information on the BPD and the UK legislation is held on a number of different websites, the following list details the main sites where information is available.

***European Chemicals Bureau*** – <http://ecb.jrc.it/biocides/>

***European Commission Environment Directorate website*** –  
<http://europa.eu.int/comm/environment/biocides/index.htm>

***HSE Biocides & Pesticides Unit website*** –  
<http://www.hse.gov.uk/biocides> ; <http://www.hse.gov.uk/pesticides>

***Her Majesty's Stationery Office*** – [www.hmso.gov.uk](http://www.hmso.gov.uk)

#### **HSE Biocides/Pesticides Contacts** - for further information please contact us :

Biocides & Pesticides Unit  
Health and Safety Executive  
Magdalen House  
Trinity Road  
Bootle  
Merseyside  
L20 3QZ

Tel: 0151 951 3535  
Fax: 0151 951 3317

e-mail [biocides@hse.gsi.gov.uk](mailto:biocides@hse.gsi.gov.uk)  
[www.hse.gov.uk/biocides](http://www.hse.gov.uk/biocides)  
[www.hse.gov.uk/pesticides](http://www.hse.gov.uk/pesticides)

HSE Books : Tel: 01787 881165      [www.hsebooks.com](http://www.hsebooks.com)